K024313

page 1 of 2

510(k) Summary

AUG 2 9 2003

Date
May 6, 2003

Submitter
Pisharodi Surgicals, Inc.
942 Wildrose Lane
Brownsville, TX 78520

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Trade name
UNIMAX Pedicle Screw System
Horizontal Offset Plate

Common name
Posterior spine system

Classification name
Spondylolisthesis Spinal Fixation Device System - class II
Pedicle Screw Spinal System - class II
888.3070 (per 21 CFR section)

Indications for Use
The UNIMAX Pedicle Screw System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar or sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusions.

As a pedicle screw system the UNIMAX Pedicle Screw System is intended for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebrae in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

Equivalent Device
This additional component is equivalent to the previous horizontal plate for the UNIMAX Pedicle Screw System in indications, usage and materials.

Device Description
The UNIMAX Pedicle Screw System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar or sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusions.

As a pedicle screw system the UNIMAX Pedicle Screw System is intended for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebrae in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The UNIMAX Pedicle Screw System consists of pedicle screws (K014302) vertical, washers, nuts and horizontal plates. It can be used for single or multiple level fixation. .

K004313
page 2 of 2

All components are manufactured from titanium alloy (Ti-6Al-4V) that conforms to ASTM F136.

The additional component that is the subject of this Special 510(k) submission is the Offset Horizontal Plate. Its purpose is to provide rigidity to the spinal construct similar to the horizontal plate cleared on K014302.

Summary Nonclinical Tests

Analysis indicates that the offset horizontal plate is as strong as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2003

Pisharodi Surgicals, Inc.
c/o Mr. J.D. Webb
The Orthomedix Group, Inc.
1001 Oakwood Boulevard
Round Rock, TX 78681

Re: K024313
Trade/Device Name: UNiversal MultiAXis (UNIMAX) Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI, MNH
Dated: July 31, 20003
Received: August 1, 2003

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

page 1 of 1

INDICATIONS / INTENDED USE STATEMENT

K 024313

510(k) Number: ~~K014302~~ (Regulatory Number: 21 CFR 888.3070)

Device Name: UNiversal MultiAXis (UNIMAX) Pedicle Screw System

Indications / Intended Use:

The Pisharodi Surgicals, Inc. UNIMAX Pedicle Screw System is intended to provide immobilization and stabilization of non-cervical posterior spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine.

When used as a pedicle screw fixation system of the non-cervical spine in skeletally mature patients, the UNIMAX Pedicle Screw System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurological impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudarthrosis).

When used as a pedicle screw fixation system the UNIMAX Pedicle Screw System is indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K024313